

REMARKS

Claims 1-37 and 87-189 are pending in the patent application. Claims 91-160 and 172-189 have been cancelled without prejudice as a result of a restriction requirement. The Applicants reserve the right to pursue these claims in other patent applications. Claims 1, 22 and 161 have been amended to recite the phrase "wherein the carbon monoxide associated with the raw meat within the first package is adapted to be removable." Support for these amendments may be found at, for example, page 12, lines 2-12 and the examples of the present application. No new matter has been entered. After entry of these amendments, claims 1-37, 87-90 and 161-171 are present in the patent application.

I. Restriction Requirement/Election

The Applicants are confirming the election to proceed with claims 1-37, 87-90 and 161-171. The remaining claims of the application (claims 91-160 and 172-189) are being cancelled without prejudice as a result of this restriction requirement.

II. 35 U.S.C. § 103(a) Rejections

The Applicants are submitting herewith evidence in the form of a 37 C.F.R. §1.132 declaration by one skilled in the art of meat processing using modified atmosphere packaging (Dr. Melvin C. Hunt) (Exhibit 1) to assist in showing the non-obviousness of the invention.

The Applicants are also submitting herewith evidence in the form of a 37 C.F.R. §1.132 declaration by one of the co-inventors Mr. Gary R. DelDuca ("the DelDuca Second Declaration") (Exhibit 2) to assist in showing the commercial success of the invention. The Applicants note that Mr. DelDuca previously submitting a declaration ("the DelDuca First Declaration")¹ to assist in explaining the invention and showing the non-obviousness of the invention.

¹ The DelDuca First Declaration was filed with the Amendment and Response to Office Action Dated May 7, 2003.

A. A *Prima Facie* Case Has Not Been Presented with Respect to Independent Claims 1, 22 and 161

The present invention is directed to novel methods of manufacturing modified atmosphere packages. The present invention does not “fix” the color of the meat pigment to red with its use of carbon monoxide (CO), but rather the meat pigment tends to turn brown in a natural time period. See page 12, lines 10-12 of the application; Hunt Decl. ¶ 6; DelDuca Second Decl. ¶ 11. It is important to prevent the meat color from being “fixed” because it is unsafe (and potentially dangerous) to consume a piece of meat that has a bright red color that consumers associate with freshness, but is beyond the point of microbial soundness. See DelDuca Second Decl. ¶ 11.

Independent claims 1, 22 and 161 recite, *inter alia*, (a) “a first package including a non-barrier portion substantially permeable to oxygen”; (b) “a second package substantially impermeable to oxygen”; (c) a low oxygen environment that includes from about 0.1 to about 0.8 vol% carbon monoxide (CO) or from about 0.3 to about 0.5 vol% CO; and (d) “wherein the carbon monoxide associated with the raw meat within the first package is adapted to be removable.” The applied references in the Office Action do not teach or suggest such limitations that are recited in independent claims 1, 22 and 161.

As acknowledged in the Office Action at page 3, U.S. Patent No. 6,054,153 to Carr (“Carr”) is silent in teaching or suggesting the use of CO. The other applied reference (U.S. Patent No. 4,522,835 to Woodruff (“Woodruff”)) does not disclose a packaging system having (a) “a first package including a non-barrier portion substantially permeable to oxygen;” and (b) “a second package substantially impermeable to oxygen,” as recited in independent claims 1, 22 and 161. In response to the deficiencies of these applied references, the Office Action stated the following:

It would have been obvious to modify Carr et al. [Carr] and include anywhere from 0.1-0.8% carbon monoxide, 40 to 80% nitrogen, and 20-60% carbon dioxide in the modified atmosphere pocket (i.e., between the two packages) to convert the deoxymyoglobin to carboxymyoglobin...since Woodruff et al. [Woodruff] teach it is preferred to have a ‘good color’ (i.e. red color of fresh meat) for meat stored with a low/no oxygen modified atmosphere and this is done by adding 0.1 to 0.8% carbon monoxide along with 40-80% nitrogen and 20-60% carbon dioxide in the package. One would have been substituting one conventional carbon dioxide/nitrogen based atmosphere for another for the same purpose: providing a

low/no oxygen atmosphere for providing the appearance of fresh cut meat after storage.

Office Action at page 4.

This passage in the Office Action ignores the understanding of those of ordinary skill in the art that CO fixes the color of the meat and there would be no motivation to one of ordinary skill in the art for using CO in a modified atmosphere such as disclosed in Woodruff with a meat packaging system such as disclosed in Carr. The problems of fixing meat color with CO, which can mask spoilage, are clearly known to those of ordinary skill in the art. *See, e.g.*, Hunt Decl. ¶ 6; DelDuca Second Decl. ¶ 11. The problem of fixing meat color with CO was described in a previously applied reference in the Office Action dated May 7, 2003 to Sorheim et al.² Furthermore, the United States Food and Drug Administration (FDA) has believed that the meat pigment color would be fixed using CO.³ Thus, the alleged “good” color (*i.e.*, red color of fresh meat) disclosed in Woodruff is not a desirable attribute when the meat pigment remains such a color past its microbial soundness. Thus, there is simply no motivation to combine Carr and Woodruff in an attempt to address the problems solved by the present invention and to read on the pending claims.

Additionally, Dr. Hunt, who has extensive experience in the processing of meat using modified atmosphere packaging, stated that “[t]he results of the testing [of the Pactiv’s improved ActiveTech® meat packaging system⁴] were surprising to me because it was understood by those skilled in the art that CO fixes (creates a stable form of myoglobin that could mask spoilage) the color of the meat pigment to red.” Hunt Decl. ¶ 6. Pactiv’s improved ActiveTech® meat

² The applied reference was “The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon dioxide” from *Meat Science* to Sorheim et al. (“Sorheim”). In particular, Sorheim disclosed that its meat packaging systems with a modified atmosphere of “0.4% CO/60% CO₂/40% N₂ had a bright stable red colour that lasted beyond the time of spoilage.” Abstract of Sorheim.

³ Exhibit 3 (In a 1962 letter, the FDA told a Whirlpool representative that it might need additional data “to establish that the treatment of meat would not serve to cause the meat to retain its fresh red color longer than meat not so treated” and that the FDA has a question “concerning possible deception of the consumer where treatment of the meat leads to longer retention of the fresh red color.”); *see also* Hunt Decl. ¶ 6

⁴ The process of Pactiv’s ActiveTech® improved meat packaging system is one process that would be covered by the pending independent claims.

packaging system did not fix the color of the meat pigment as expected and Dr. Hunt stated that “[t]his was a novel result and was not at all obvious due to the current and long standing thought that meat exposed to CO would develop a color that would mask spoilage.” *See id.*

One of the other applied references (U.S. Patent No. 5,711,978 to Breen (“Breen”)) has the same deficiencies as Carr. Specifically, Breen does not disclose the use of CO in its respective packaging system, let alone the claimed amount of CO recited in the independent claims. Breen discloses the use of a “substantially pure carbon dioxide” environment. *See, e.g.*, col. 5, lines 10-14. The other applied reference (the abstract DE 1935566 to Verbruggen (“Verbruggen”)) has the same deficiencies of Woodruff in that it simply discloses the use of CO and meat without discussing a packaging solution.

Thus, there is no motivation to combine the references of Carr, Woodruff, Breen, Verbruggen, or any combination thereof in an attempt to read on the pending claims. The mere fact that references can be combined together or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990). “When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references.” *See Rouffet*, 149 F.3d at 1355, 47 U.S.P.Q.2d at 1456, (citing *In re Geiger*, 815 F.2d 686, 688; 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987)). Evidence of a suggestion, teaching, or motivation to combine “must be clear and particular.” *See Ex parte Maruyama*, 2001 WL 1918556, *3 (Bd. Pat. App. & Inter. 2001), (citing *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352; 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998)).

Obviousness cannot “be established using hindsight or in view of the teachings or suggestions of the invention.” *Ex parte Maguire* (Appendix 9), 2002 WL 1801466, *4 (Bd. Pat. App. & Inter. 2002), (quoting *Para-Ordnance Mfg. Inc. v. SGS Imps. Int’l Inc.*, 73 F.3d 1085, 1087, 37 U.S.P.Q.2d 1237, 1239 (Fed. Cir. 1995), *cert. denied*, 519 U.S. 822 (1996)). In other words, the knowledge to combine “can not come from the applicant’s invention itself.” *In re Oetiker*, 977 F.2d 1443, 1447, 24 U.S.P.Q.2d 1443, 1446 (Fed. Cir. 1992) (emphasis added).

Thus, the Applicants believe that a *prima facie* case has not been presented with Carr, Woodruff, Breen, Verbruggen, or any combination thereof.

B. Evidence of Non-Obviousness of Independent Claims 1, 22 and 161

Assuming, *arguendo*, that a *prima facie* case has been presented (which Applicants believe is not the case), the Applicants are submitting evidence of non-obviousness in the form of two declarations – the Hunt Declaration (Exhibit 1) and the DelDuca Second Declaration (Exhibit 2) to assist in showing the non-obviousness of the invention.

i. CO Not Allowed with Fresh Meat in the United States Since At Least 1962

CO had not been allowed to be used with fresh meat in the United States for about 40 years. *See* Exhibit 3 (1962 Whirlpool letter); DelDuca Second Decl. ¶ 11. The concern of the FDA is believed to be that CO fixes the fresh meat color to a degree that allows the retailer to sell meat that looks good (a bright red color), but is beyond the point of microbial soundness. *Id.*

ii. CO Now Allowed In Pactiv's Improved ActiveTech® Meat Packaging System

After about 40 years of not allowing CO to be used with fresh meats in the United States, the Applicants came up with novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoided the concerns of “fixing” the meat color. DelDuca Second Decl. ¶ 11.

The specific MAP system that was presented in the GRAS notice was Pactiv's improved ActiveTech® meat packaging system. The improved ActiveTech® meat packaging system included meats being placed in polystyrene trays and covered with oxygen-permeable, polyvinyl chloride (“PVC”) overwraps. DelDuca Second Decl. ¶ 5. The wrapped trays of meat are then placed in an outer barrier bag. Ambient air is removed and replaced with a blend of 0.4% CO, 30% carbon dioxide, and the balance being nitrogen. *Id.*

The FDA stated that it had no questions regarding Pactiv's conclusion about Pactiv's improved ActiveTech® meat packaging system using 0.4% CO being GRAS because of the evidence presented by Pactiv in its notice. DelDuca Second Decl. ¶ 12. This FDA review allows Pactiv to use CO with fresh meat in its application. *Id.* It is believed to be the first system to overcome the prohibition of CO with fresh meat in the United States in the last 40 years. *Id.*

Thus, a problem of fixing meat color with CO that was recognized for at least the last 40 years was overcome by Pactiv's improved ActiveTech® meat packaging system and process of the same. The process of manufacturing using Pactiv's improved ActiveTech® meat packaging system is an example of a process that would be covered under independent claims 1, 22 and 161 of the present application. *Id.* at 10.

iii. The Pactiv Improved ActiveTech® Meat Packaging System and Process Addresses a Long-Felt Need

The Federal Circuit has stated that if an invention unexpectedly solved longstanding problems, it supports the conclusion of nonobviousness. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1382 (Fed. Cir 1986); *WMS Gaming Inc. v. Intl.Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999).

The process of manufacturing Pactiv's improved ActiveTech® meat packaging system, which is an example of a process that would be covered under independent claims 1, 22 and 161 of the present application, addressed such a long-felt need in the meat-packaging industry. "Prior to Pactiv's [improved] ActiveTech® meat packaging system using 0.4 vol.% CO, there was a need in the industry to provide a solution that: (a) reduced the seasoning period (the critical time meat is exposed to low partial pressures of oxygen, which can seriously damage the pigment chemistry); (b) formed consistently a normal bloomed color with meats whose pigment is sensitive to metmyoglobin formation; and (c) avoided the fixing of too stable of a meat color, which can be unsafe and potentially dangerous, if the color stability was greater than the shelf life (microbial soundness) of the product." Hunt Decl. ¶ 7. "Such a solution was especially desirable for a centralized packaging facility where the meat would be shipped to distant locations." *Id.* "Pactiv's [improved] ActiveTech® meat packaging system using 0.4 vol.% CO was a new and novel approach that addressed these technological needs." *Id.* Dr. Hunt stated that the results of the testing of Pactiv's ActiveTech® meat packaging system were surprising. *See id.* at ¶¶ 5,6.

Thus, since Pactiv's improved ActiveTech® meat packaging process surprisingly addressed a long-felt need, this is further evidence that the independent claims of the present application are not obvious over the applied references.

iv. The Pactiv Improved ActiveTech® Meat Packaging System and the Process of Using the Same is Commercially Successful

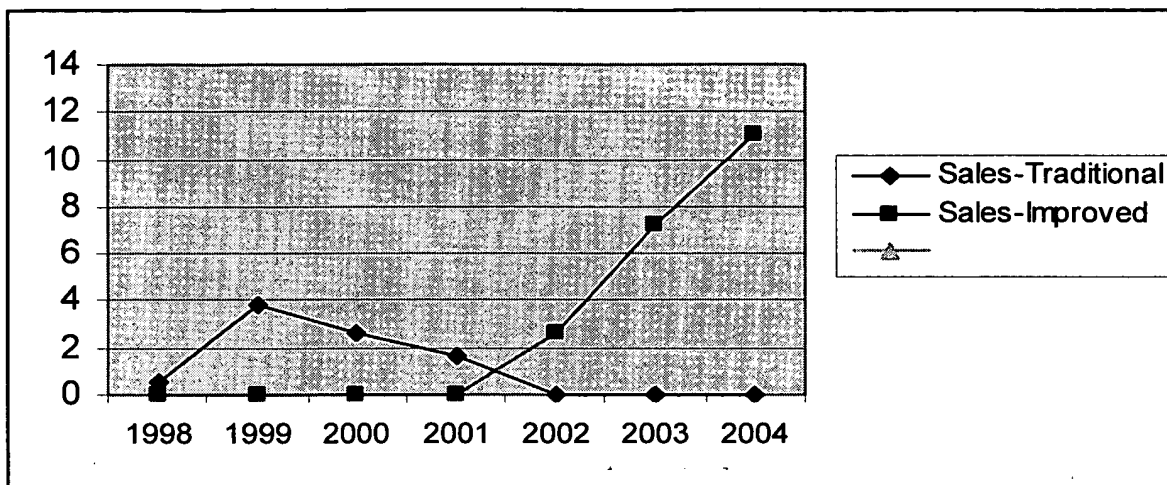
The Federal Circuit has also stated that “[c]ommercial success is ... a strong factor favoring non obviousness.” *See, e.g., Akzo N.V. v. U.S. Int’l Trade Comm’n*, 808 F.2d 1471, 1481 (Fed. Cir. 1986); *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1580 (Fed. Cir. 1997).

The process of manufacturing using Pactiv’s improved ActiveTech® meat packaging system, which is one process that would be covered under independent claims 1, 22 and 161, has been commercially successful. DelDuca Second Decl. ¶ ¶ 8,10. This is shown by the commercial sales of Pactiv’s improved ActiveTech® meat packaging system. *Id.*

Pactiv sold modified atmosphere packaging systems (without using CO) beginning in 1998 (the traditional ActiveTech® meat packaging system). DelDuca Second Decl. ¶ 4. Beginning in March of 2002, Pactiv began offering for sale an improved ActiveTech® meat packaging system. *Id.* at ¶ 5. Pactiv’s improved ActiveTech® meat packaging system uses 0.4 vol.% CO, while Pactiv’s traditional ActiveTech® meat packaging system does not use CO. *Id.*

As shown below in the Graph, sales of Pactiv’s traditional ActiveTech® meat packaging system were decreasing in 2000 and 2001. *Id.* at ¶ 8. The sales of Pactiv’s improved ActiveTech® meat packaging system, however, have substantially increased since its introduction in March of 2002. *Id.* The sales of Pactiv’s improved ActiveTech® meat packaging system have been commercially successful as shown by the sales of over 7 million dollars in 2003 and an estimated sales of 11 million for 2004. *Id.*

GRAPH



Since March of 2002, both Pactiv's improved ActiveTech® meat packaging system and Pactiv's traditional ActiveTech® meat packaging system have been available for sale. *Id.* at ¶ 9.

Since March 2002, no customer has purchased Pactiv's traditional ActiveTech® meat packaging system. *Id.* It can be concluded that these customers prefer Pactiv's improved ActiveTech® meat packaging system over Pactiv's traditional ActiveTech® meat packaging system. The cost of Pactiv's improved ActiveTech® meat packaging system versus Pactiv's traditional ActiveTech® meat packaging system is fractionally more expensive. *Id.* Thus, the commercial success of Pactiv's improved ActiveTech® meat packaging system cannot be attributed to a cost advantage. *Id.*

Thus, since the process of manufacturing Pactiv's improved ActiveTech® meat packaging process has been commercially successful, this is further evidence that the independent claims of the present application are not obvious over the applied references.

Therefore, in addition to the applied references not presenting a *prima facie* case, the Applicants also believe that the present invention is allowable because of the compelling evidence of non-obviousness. Therefore, independent claims 1, 22 and 161 are not obvious in view of Carr, Woodruff, Breen, Verbruggen or any combination thereof and, thus, should be in a condition for allowance.

C. Dependent Claims 2-21, 23-37, 87-90 and 162-171

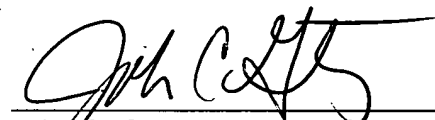
Dependent claims 2-21, 23-37, 87-90 and 162-171, which depend directly or indirectly on independent claim 1, 22 or 161, are not obvious in view of Carr, Woodruff, Breen, Verbruggen or any combination thereof for at least the same reasons discussed with respect to claims 1, 22 and 161. Thus, claims 2-21, 23-37, 87-90 and 162-171 should be in a condition for allowance.

D. Conclusion

The Applicants submit that the claims are in a condition for allowance and action toward that end is earnestly solicited. No new matter has been entered. The Applicants have included a complete listing of all the claims, including the cancelled and withdrawn claims. Thus, the amendment should be in proper form. The Applicants respectfully request that the amended claims be entered and the application be reviewed in view of the following comments. It is believed that no further fees are due; however, should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from Jenkins & Gilchrist, P.C. Deposit Account No. 10-0447, Order No. 47097-01080.

Respectfully submitted,

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